unknown, the petition should state this.

(2) Petitioners submitting exemption requests for substances normally used on or taken into the human or animal body shall, in addition to the requirements of paragraphs (a) and (b)(1) of this section, submit an evaluation of the pharmacology and toxicology of the substance in question based on reasonably available medical and scientific literature. The evaluation should be a comprehensive one, and should include proper literature citations. To the extent possible, information submitted by the petitioner justifying an exemption based on the medical and scientific literature will be evaluated under the criteria specified in §1702.9(a) for evaluating experimental data. In certain cases where the experimental data specified by §1702.9 (a) and (b) are unavailable, the medical and scientific literature may justify granting an exemption, particularly where the pharmacology and toxicology of the substance is well documented in the literature.

(c) *Optional data criteria for petitions involving substances not used in or on the human or animal body.* The following types of data, although often not generated for household substances not normally used in or on the human or animal body, may be available to a petitioner and should, where reasonably available, be submitted.

(1) Summary laboratory reports of data obtained in subacute and chronic animal studies where such data pertain to the absorption, distribution, metabolism, and excretion of the substance in question;

(2) Results of median lethal dosage (LD50) studies conducted in additional species of animals; and

(3) Any additional experimental studies relevant to the exemption request which would provide the Commission with additional means of assessing the hazards to children of the product for which exemption is sought.

§ 1702.10 Human experimental data involving the testing of human subjects.

Any human experimental data submitted with a petition requesting an exemption under this part shall include a statement establishing that adequate measures have been taken to ensure against psychological or physical injury to the subject of the human studies. The Commission considers its regulations concerning the protection of human subjects (16 CFR part 1028) to be an example of measures that are adequate to ensure against psychological or physical injury to human subjects.

§ 1702.11 Product specifications.

Each petition for an exemption shall include:

(a) A complete quantitative formula for the product, including inert ingredients, diluents, and solvents. (Petitioners should refer to §1702.6 for information regarding trade secrets.)

(b) A listing of all physical forms or dosage forms (whichever is appropriate) in which the product is available.

§ 1702.12 Packaging specifications.

Each petition for an exemption shall include the following information for each form of the product for which an exemption is sought:

(a) A description of the packaging currently in use including the name of the manufacturer of the package and all specifications for the package,

(b) A complete packaging description including any carton or wrapping in which the product is offered to the consumer,

(c) A description of each size in which the product is offered, including physical form, color and flavoring, and

(d) An empty sample of each type and size of package petitioned for exemption and, in the case of drugs, a designation of those packages intended to be used in dispensing the product to the consumer for household use.

§ 1702.13 Labeling and packaging samples.

Each petition for an exemption under this part shall include a sample of the label and complete packaging for each size in which each form of the product for which an exemption is sought is packaged. This shall include the immediate container labeling, any package inserts, and other carton or wrapping labeling in which the product is offered to the consumer. In the case of drugs,